भारतीय मानक
Indian Standard

IS 17629 : 2021

चिकित्सीय वस्त्रादि — कैप — विशिष्टि

Medical Textiles — Caps — Specification

ICS 11.040.30; 59.080.99

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भारतीय मानक ब्यूरो
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September 2021 **Price Group 3**

Technical Textiles for Medtech Applications Sectional Committee, TXD 36

FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Technical Textiles for Medtech Applications Sectional Committee had been approved by the Textiles Division Council.

Caps are worn as personnel protective clothing for head covering by surgeon, operating room staff and other healthcare professional. Caps are helpful to prevent contamination of the operating field, patient and materials from microorganisms/particulates that originate in the personnel's hair or scalps.

The composition of the Committee responsible for the formulation of this standard is given in Annex B.

For the purpose of deciding whether a particular requirement of this standard is complied with the final value, observed or calculated expressing the result of a test or analysis shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

Indian Standard

MEDICAL TEXTILES — CAPS — SPECIFICATION

1 SCOPE

1.1 This standard specifies the requirements for caps intended to be worn by surgeon, operating room staff and other healthcare professional during the surgical and other invasive procedures to prevent contamination of the operating field, patient and materials from transfer of hair, microorganisms, particulates etc. They can be single use or re-useable.

1.2 These caps are also known by other nomenclature, such as operation theater cap, surgeon cap, surgeon hood, head cover, bouffant cap, nurse cap etc.

2 REFERENCES

The standards listed in Annex A contain provisions which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated in Annex A.

3 TERMS AND DEFINITIONS

For the purpose of this standard, the following term shall apply:

3.1 Cleanliness-Microbial — Freedom from population of viable microorganism on a product and/ or a package.

3.2 Cleanliness-Particulate Matter — Freedom from particles that are contaminating a material and can be released but are not generated by mechanical impact.

3.3 Colony Forming Unit (CFU) — Unit by which culturable number of microorganisms is expressed.

3.4 Dry Microbial Penetration — Migration of microorganisms through a barrier material in dry state.

3.5 Manufacturer — Natural or legal person with responsibility for the processing of raw material or inputs in any manner that results in the emergence of a new product having a distinct name, character and use.

3.6 Particle Release — Particle release from fiber fragments and other particles during mechanical stress.

3.7 Reusable Product — Product intended by the manufacturer to be reprocessed and reused.

3.8 Single-use Product — Product intended by the manufacturer to be used only once.

4 MANUFACTURE

4.1 The cap shall be made from suitable textile material that is not prohibited for use for the purpose under any applicable law/regulation in force so that the product made out of this meets the requirements specified in this standard.

4.2 The caps shall be provided with elastic strip or any other suitable mechanism for secure fit and proper fastening.

4.3 The caps should be breathable and may be supplied in non-sterile or in sterilized condition as per the requirement of the buyer.

5 WORKMANSHIP AND FINISH

The size and color of the cap shall be as per the agreement between buyer and seller. The caps shall be clean and free from substances liable to cause tendering during storage. The manufacture and preparation of the cap shall be conducted under proper hygienic conditions.

6 WASHING, DRYING AND HANDLING INSTRUCTION

The manufacturer shall provide the washing, drying, handling, storage and sterilization instruction on every packet of reusable cap to ensure proper use and care by the user.

7 REQUIREMENTS

7.1 The cap shall conform to the requirements specified in Table 1. The performance requirements of reusable products shall have to be met after declared wash and sterilization cycle as specified in Table 1.

Table 1 Requirements for Caps

(*Clause* 7.1)

Sl No.	Characteristics	Requirement	Method of Test, Ref to
(1)	(2)	(3)	(4)
i)	Cleanliness – Microbial (CFU/100 cm^2)	≤ 300	ISO 11737-1
ii)	Tensile strength (Dry and wet) (N)	≥ 20	Nonwoven, IS 15891 (Part 3), Woven, IS 1969 (Part 1)
iii)	Bursting strength (Dry and wet) (kPa)	≥ 40	IS 1966 (Part 1)
iv)	Particle release [log10 (lint count)]	≤ 4.0	IS 15891 (Part 10)
v)	Resistance to microbial penetration — Dry (CFU)	≤ 300	IS 16548
vi)	Moisture vapour transmission rate (*Max*.) (*optional*) (*see note*)	40 m^2 Pa/W	IS 17376

NOTE — Moisture vapour transmission is the ability of water vapour to pass through a material. This attribute has a significant effect on comfort, because materials without the ability to allow moisture transmission are generally uncomfortable. This test is recommended to be performed for caps that are being used in high risk surgeries with prolonged duration where the doctors/healthcare personnel are subjected to heat stress due to which they may feel uncomfortable.

8 PACKING

The caps shall be packed securely so as to allow normal handling and transport without tearing and exposing the contents. Details of the packing shall be as agreed to between the buyer and the seller. Packaging of the product should be, such as to maintain the integrity of the product throughout its shelf life.

9 MARKING

9.1 Each pack of the caps shall be legibly and indelibly marked with following information:

a) Name of the product;
b) Dimension/size of the product;
c) Manufacturer’s name, initials or trademark, if any;
d) Month and year of manufacture, batch/lot number;
e) Washing, drying and care instruction, if the product is reusable;
f) Declared life cycle/maximum wash cycle, if the product is reusable;
g) Country of origin;
h) Sterilized or un-sterilized;
j) If the product is reusable, information on the appropriate processes to allow reuse, the method of re-sterilization;
k) If the product is multiple use, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of re-sterilization and any restriction on the number of reuses. Where products are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the device will still comply with “the essential principles of safety and performance of medical devices”; and
m) Any other statutory requirement as required by the law in force.

9.2 BIS Certification Marking

The product(s) conforming to the requirements of this standard may be certified as per the conformity assessment schemes under the provisions of the *Bureau of Indian Standards Act*, 2016 and the Rules and Regulations framed thereunder, and the product(s) may be marked with the Standard Mark.

10 SAMPLING AND CRITERIA FOR CONFORMITY

10.1 Lot

All the caps of the same material and dimensions produced under similar conditions of manufacture and sterilization shall constitute a lot.

10.1.1 Each lot shall be tested separately for ascertaining the conformity of the lot.

10.1.2 Unless otherwise agreed, the number of caps to be selected from the lot shall depend on the size of the lot and shall be in accordance with column 2, column 3 and column 5 of Table 2.

10.1.3 These caps shall be selected at random from the lot. For this purpose, reference may be made to IS 4905.

10.2 Number of Tests and Criteria for Conformity

10.2.1 All the caps selected as per column 3 of Table 2 shall be examined for workmanship and finish (*see* **5**).

10.2.1.1 Any caps failing in one or more of the above requirements shall be termed as defective. The lot shall be considered as conforming to the above requirements, if the total number of defectives found in the sample is less than or equal to the acceptance number given in column 4 of Table 2. Otherwise, the lot shall be rejected.

Table 2 Number of Caps to be Selected

(*Clause* 10.1.2, 10.2.1, 10.2.1.1, 10.2.2 *and* 10.2.3)

Sl No.	**Lot Size**	**Non-Destructive Testing**		**Destructive Testing**	
		No. of Caps to be Selected	Acceptance Number	No. of Caps to be Selected	Acceptance Number
	N	n	a	n_1	a_1
(1)	(2)	(3)	(4)	(5)	(6)
i)	Up to 280	13[1]	1	8	0
ii)	281 to 500	20	2	8	0
iii)	501 to 1200	32	3	13	0
iv)	1201 to 3200	50	5	13	0
v)	3201 and above	80	7	20	1

[1] or lot size when less than 13.

10.2.2 Out of the sample already found satisfactory according to **10.2.1.1**, a sub-sample as per column 5 of Table 2 shall be taken. This sub-sample shall be further tested for the remaining requirements.

10.2.3 The lot shall be considered as conforming to the requirements of the specification if the total number of defective products found in the sample (as per **10.2.2**) is less than, or equal to the acceptance number as given in column 6 of Table 2.

ANNEX A

(*Clause* 2)

LIST OF REFERRED INDIAN STANDARDS

IS/ISO No.	*Title*
1966 (Part 1) : 2009	Textiles — Bursting properties of fabrics determination of bursting strength and bursting distension: Part 1 Hydraulic method (*second revision*)
1969 (Part 1) : 2018	Textiles — Tensile properties of fabrics: Part 1 Determination of maximum force and elongation at maximum force using the strip method (*fourth revision*)
4905 : 2015	Random sampling and randomization procedures (*first revision*)
15891 (Part 3) : 2011	Textiles — Test methods for nonwovens: Part 3 Determination of tensile strength and elongation
15891 (Part 10) : 2017	Textiles — Test methods for nonwovens: Part 10 Lint and other particles generation in dry state
16548 : 2016	Clothing for protection against infectious agents — Test method for resistance to dry microbial penetration
17376 : 2020/ ISO 11092 : 2014	Textiles — Determination of physiological effects — Measurement of thermal and water-vapour resistance under steady-state conditions (sweating guarded-hot plate test)
ISO 11137-1 : 2006	Sterilization of health care products — Radiation: Part 1 Requirements for development, validation and routine control of a sterilization process for medical devices

ANNEX B

(*Foreword*)

COMMITTEE COMPOSITION

Technical Textiles for Medtech Applications, TXD 36

Organization	*Representative(s)*
The South India Textile Research Association, Coimbatore	Dr Prakash Vasudevan (***Chairman***)
3 M India Limited, New Delhi	Shri Kulveen Singh Bali Shrimati Prabha Hegde (*Alternate*)
Association of Indian Medical Devices (AiMeD), New Delhi	Dr G. D. Agarwal Shri Jitendra Sachchade (*Alternate*)
All Indian Institute of Medical Sciences, New Delhi	Dr Vijaydeep Siddharth Dr Anoop Daga (*Alternate*)
Business Coordination House, New Delhi	Shri Sameer Gupta Shrimati Ritika Gupta (*Alternate*)
Cologenesis Healthcare Pvt Ltd, Salem	Shri R. Krishnakumar Shri K. Ramprasad (*Alternate*)
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DGAFMS, Ministry of Defence, New Delhi	Col Ramesh Chandra Surg Lt Cdr Kotian V. Gopal (*Alternate*)
DGQA (Ministry of Defence), New Delhi	Shri Senthil Kumar Shri Arnab Das (*Alternate*)
Director General of Health Services, New Delhi	Dr Inder Prakash Dr Sunny Swarnkar (*Alternate*)
M/s Dispoline India Private Limited, Bengaluru	Shri Sumit Marwah.
Dr Sabharwals Manufacturing Labs Pvt Ltd, Panchkula	Shri Manish Sabharwal Shri Dhruv Sabharwal (*Alternate*)
Federation of Indian Chambers of Commerce & Industry, New Delhi	Dr Sanjiiv Rehlan Ms Tulsi (*Alternate*)
Ginni Filaments Limited, Noida	Shri Pramod Sharma
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Indian Institute of Technology, New Delhi	Prof Ashwini Agarwal Prof Vipin Kumar (*Alternate*)
Indian Technical Textile Association, Mumbai	Dr Anup Rakshit Mr Mahesh Kudar (*Alternate*)
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Kamal Healthcare Pvt Limited, Tamilnadu	Shri S. Sankar Marimuthu
KOB Medical Textiles Pvt Ltd, Palladam	Shri Arun Buchade Shri S. Kumar Subramanian (*Alternate*)
Livinguard Technologies Pvt Ltd, Mumbai	Ms Shivani Swami Dr Shefali Mishra (*Alternate*)

Organization	*Representative(s)*
Maulana Azad Medical College, New Delhi	Dr P. N. Agarwal Dr U. C. Verma (*Alternate*)
Medline Healthcare Industries Pvt Ltd, Pune	Mr Anthony Dcosta Shri Dhaval Ghuge (*Alternate*)
National Physical Laboratory, New Delhi	Dr Sanjay Yadav Dr Shankar G. Aggarwal (*Alternate*)
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Office of the Textile Commissioner, Mumbai	Shri Sivakumar S. Shri Narrotam Kumar (*Alternate*)
PGIMER, Chandigarh	Dr Pankaj Arora
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Surgicotfab Textile Pvt Ltd, Ahmedabad	Shri Paresh Patel
Textiles Committee, Mumbai	Shri Kartikeyan Dhanda Ms Shilpi Chauhan (*Alternate*)
The Bombay Textile Research Association, Mumbai	Shrimati Aruna Apte
The South India Textile Research Association, Coimbatore	Dr E. Santhini Shri Veera Subramaniam (*Alternate*)
The Synthetics and Art Silk Mills Research Association, Mumbai	Dr Manisha Mathur Shrimati S. S. Dongre (*Alternate*)
Vimta Lab Limited, Hyderabad	Dr Mukesh Agrawal Shri Jagadeesh Kodali (*Alternate*)
BIS Directorate General	Shri A. K. Bera, Scientist 'F' and Head (TXD) [Representing Director General (*Ex-officio*)]

Member Secretary

Shri Dharmbeer
Scientist 'C' (TXD), BIS

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